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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,539	08/22/2003	Jay Douglas Audett	ARC3254R1/A5033	9721
27777	7590	04/04/2007		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER CHANG, VICTOR S	
			ART UNIT	PAPER NUMBER
			1771	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/04/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/646,539

Applicant(s)

AUDETT, JAY DOUGLAS

Examiner

Victor S. Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007 and 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 14-16, 18-23 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-16, 18-23 and 25-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Introduction***

1. Applicants' amendments and remarks filed on 11/13/2006 have been entered previously (see Office action mailed 1/16/2007). 14-16, 18-23 and 25-31 are active.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Rejections not maintained are withdrawn. Applicants' remarks directed to withdrawn references are moot.

### ***Election/Restrictions***

4. Applicant's election with traverse of claims 14-16, 18-23 and 25-30 in the reply filed on 2/8/2007 is acknowledged. The traversal is on the ground(s) that claim 14 and claim 31 can be efficiently searched without undue burden. This is not found persuasive because the species are structurally distinct and are patentable over each other. Moreover, there is no evidence that these species are obvious variants, therefore additional search would be required.

The requirement is still deemed proper and is therefore made FINAL.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

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application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 14-16, 18-23, 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 13, 21, 43, 54-57, 66, 90-92, 97-99 of copending Application No. 10/420,428 in view of Steinborn et al. [US 6080421]. More particularly, the copending Appl. '428 discloses the structure and composition of the instant invention except that Appl. '428 is silent about that the outer layer is embossed. However, prior art Steinborn's invention relates to a multilayer transdermal identified without printing inks, and discloses that embossing or printing are known methods to label transdermal therapeutic systems. It would have been obvious to label the invention of copending Appl. '428 with the embossing method of Steinborn, motivated by the desire to be able to identify the device.

This is a provisional obviousness-type double patenting rejection.

***Rejections Based on Prior Art***

7. Claims 14, 15, 18-23, 25, 26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kydonieus et al. [US 4758434] in view of Steinborn et al. [US 6080421], and evidenced by Gale et al. [US 4904475].

Kydonieus' invention relates to an article for administration of pharmacologically active substances (drugs) transdermally, orally, etc. [abstract]. Fig. 4 shows an embodiment comprises a backing layer 34, a reservoir layer 35, a diffusion membrane layer 36. The diffusion membrane layer 36 may be made of LLDPE (linear low density polyethylene) [col. 9, lines 38-42]. The backing is made of plastic, fabric, or aluminum foil [col. 9, lines 4-5].

For claims 14, 19, 25 and 30, Kydonieus' backing layer 34, reservoir layer 35 and diffusion membrane layer 36 read on the outer layer, tie layer and base layer of instant invention, respectively. Kydonieus is silent about an embossed outer layer. However, Steinborn's invention relates to a transdermal drug delivery system and discloses that embossing is a known procedure for labeling (identifying) a transdermal drug delivery system [col. 2, lines 7-8]. It would have been obvious to one skilled in the art of transdermal drug delivery system to emboss the outer layer of Kydonieus' transdermal delivery system, motivated by the desire to be able to identify the system, and renders the instant invention obvious. As to the use language in the preamble, since it fails to contribute or limit the structure and/or composition of the device, it has not been given patentable weight, particularly when one considers applicant's own disclosure [specification, paragraph 0032] that the secondary drug reservoir may contain a beneficial agent or an antagonist.

For claim 15, in the absence composition for the component layers in the tie layer, they are indistinguishable, and therefore fail to preclude that a single tie layer of Kydonieus' embodiment in Fig. 4 reads on all the instantly claimed component layers.

For claims 18, 23 and 28, Kydonieus teaches that the backing layer 34 may also be a semi-permeable membrane, which clearly encompasses a microporous backing material [col. 9, line 51]. Further, the examiner takes Official notice that polypropylene microporous membrane is a common backing material for a transdermal delivery system.

For claims 20 and 26, Kydonieus discloses that the reservoir layer is a pharmacologically active agent containing plastisol (polymer matrix). Regarding the term "antagonist", since it is merely a relative term opposite to "primary drug", in the absence of its composition it is read upon by Kydonieus' "pharmacologically active agent". For example, while drugs such as naltrexone, etc., are categorized as an "antagonist" (see claim 26 of instant invention), the same compositions are disclosed as drugs being delivered transdermally, i.e., primary drugs, as evidenced by prior art reference Gale et al. [col. 3, line 6]. Finally, Kydonieus' pharmacologically active agent clearly encompasses the claimed pharmaceutically acceptable salts.

For claims 21 and 22, Kydonieus discloses that pharmacologically active agents are dispersed in high concentrations in a plastisol formed by fusing PVC particles and plasticizers at elevated temperature (thermoformed) [col. 3, lines 54-55 and col. 2, lines 47-51], and the examiner takes Official notice that dispersing particulate pharmacologically active agents in a polymer matrix for transdermal delivery system in not dissolved state is common and well known.

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8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kydonieus et al. [US 4758434] in view of Steinborn et al. [US 6080421] and FR 2249148 [Derwent abstract].

The teachings of Kydonieus and Steinborn are again relied upon as set forth above.

For claim 16, Kydonieus lacks a teaching of a multilayer tie layer between the backing layer 34 (outer layer) and the reservoir layer 35. However, prior art FR '148 discloses that it is known that an adhesive tape of PET film having non-tacky hot melt EVA coating on both sides is used to join two surfaces and forms a bond by heat treatment. Since Kydonieus infers in an alternative embodiment in Fig. 1 that disposing an adhesive layer between the backing layer and plastisol reservoir layer is a desirable alternative laminate structure, it would have been obvious to one of ordinary skill in the art to modify Kydonieus with an multilayered adhesive tape of FR '148 between the backing layer and the reservoir layer as well, motivated by the desire to provide an improved adhesion between the laminated layers, and an improved backing strength.

9. Claims 27 and 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kydonieus et al. [US 4758434] in view of Steinborn et al. [US 6080421].

The teachings of Kydonieus and Steinborn are again relied upon as set forth above.

For claims 27 and 29, alternatively, Kydonieus' backing layer 34, reservoir layer 35 and diffusion membrane layer 36 read on the base layer, tie layer and outer layer of instant invention, respectively. Since Kydonieus discloses that the backing layer 34 can be made of aluminum foil, it is inherently impermeable to drugs [col. 9, lines 4-5]. Again, regarding the use language in the claim, since it fails to contribute or limit the structure and/or composition of the device, it has not been given patentable weight. In particular, since the term "antagonist" merely a relative term

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opposite to "primary drug", and the same drug may be categorized differently in different conditions, therefore it fails to contribute structural limitation.

***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Victor S Chang  
Examiner  
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3/30/2007